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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,226	02/12/2004	Malcolm Peet	P64234US4	2624

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,226	PEET ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A Preliminary Amendment filed February 12, 2004 is acknowledged. Claims 1-27 are canceled. New claims 28-64 are presented and represent all of the claims now under consideration.

Information Disclosure Statements filed February 12, 2004 and August 26, 2004 are further acknowledged and have been reviewed.

Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 28 requires at least 90% of all fatty acids in the form of EPA. Therefore, the amount of DHA, AA and/or DP-n-3 content must be less than 10%.

Claims 28-37 and 39-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the treatment of any psychiatric disorder, other than schizophrenia, a schizoaffective disorder or a schizotypal disorder, and any neurological or neurodegenerative disorder, other than Huntington's disease. The specification provides support for the treatment of depression, schizophrenia and Huntington's disease comprising administering ethyl-EPA.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of any psychiatric disorder, other than schizophrenia, a schizoaffective disorder or a schizotypal disorder, and any neurological or neurodegenerative disorder, other than Huntington's disease.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of neurology.

Each particular neurologic disease or disorder has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a combination of agents, such as eicosatetraenoic acid and docosapentaenoic acid, is employed. The broad recitations "treating a psychiatric disorder, other than schizophrenia, a schizoaffective disorder or a schizotypal disorder", and "treating a neurological or neurodegenerative disorder, other than Huntington's disease" are inclusive of many conditions that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any psychiatric, neurological or neurodegenerative disease and disorder, other than the recited two recited exclusions.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of ethyl-EPA for the treatment of severe depression, schizophrenia or Huntington's disease.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular pharmaceutical preparation would be preferred for treatment of the many other psychiatric, neurological or neurodegenerative that are encompassed in the language of the claims, besides schizophrenia, depression and Huntington's disease. The skilled artisan would expect

the activity of a compound such as EPA, or the interaction of a particular combination of drugs when EPA is combined with another fatty acid, in the treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding or any criteria for extrapolating beyond the administration of ethyl-EPA. No clear direction is provided to treat other conditions. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent, or combination of agents, to treat any particular psychiatric, neurological or neurodegenerative disease, one skilled in the neurology art would have to test extensively many pharmaceutical preparations comprising EPA to determine which particular disorder responds to that particular therapy. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitations in claims 36 and 37, respectively, "an appropriate bioavailable EPA derivative which raises EPA levels in the subject" and "EPA in the form of a 2-substituted derivative or other derivative which reduces the rate of oxidation without

impairing its biological activity" render the claims indefinite. The metes and bounds of these "derivatives" cannot be precisely determined. Applicants should recite the EPA compounds contemplated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-45 and 52-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin et al., WO 98/16216.

Horrobin teaches the administration of fatty acids, as EPA, preferably more than 70% by weight, optionally in combination with other fatty acids, such as DHA, in the treatment of psychiatric disorders, such as depression, as well as in the treatment of neurologic or neurodegenerative disorders, such as dementias or tardive dyskinesia. See claim 8, page 9. The open language of the present claims allows for the inclusion of any number of additional active agents. One skilled in the neurology art would readily be able to identify an individual who is at risk, suffering from or exhibiting one of the contemplated psychiatric, neurological or neurodegenerative disorders. The claims differ in that Horrobin fails to recite the presently claimed dosages or dosage forms. However, in view of the teaching of Horrobin, one skilled in the art of formulation chemistry would have been motivated to prepare and administer compositions comprising EPA, optionally in combination with another fatty acid, for treatment of various psychiatric or neurological disorders. Such would have been obvious in the

absence of evidence to the contrary because such determinations of EPA, or other fatty acids, as well as optimal dosage forms, dosing regimens and dosages are well within the purview of those skilled in the art through no more than routine experimentation. Multiple drug therapy in the treatment of the recited psychiatric or neurological diseases is conventional.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

August 21, 2005